NOV - 8 2011 K111692

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SOMATEX®
Medical Technologies GmbH
Rheinstrasse 7 d
D-14513 Teltow / Germany

Titel:
TUMARK® Flex

May 30 , 2011

Submitter	SOMATEX® Medical Technologies GMBH Rheinstrasse 7 d D-14513 Teltow Germany Frank Kniep General Manager Telefon: ++49 3328 / 30 76 0 FAX: ++49 3328 / 30 76 99 E-mail: info@somatex.com
Application correspondent (consultant)	Harald Jung General Manager JUNG Consulting Unterer Winkel 3 D-78573 Wurmlingen Germany Telefon +49 7461-96 92 36 FAX +49 7461-96 92 37 E-mail: hjung@harald-jung.de
Trade Name	TUMARK® Flex
Common Name	Tissue Site Marking System
Classification Name	Radiographic Implantable Marker, 21 C.F.R. 878.4300
Regulatory Class:	II
Product Code :	NEU
Performance Standards	No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for Tissue Site Marking Systems.

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Summary of Safety and Effectiveness

Legally marketed (unmodified) device:

The predicate device is the TUMARK® Professional Tissue Site Marking System, [K073095, March 19, 2008] and the TUMARK® Professional / MRI TUMARK® Professional Tissue Site Marking System, [K093064, February 17, 2010]

Device Description (new devices):

The TUMARK® Flex is a sterile, single use, preloaded tissue site marking system consisting of a non–absorbable Nitinol clip-marker, a guide wire or tube and a handle with ejection mechanism. The guide wire is composed of a flexible tube, a distal ramp made of surgical high-grade steel with an opening for releasing the clip marker and a depth stopper with snap-in tip. The guide tube is composed of a tube section, a distal ramp made of surgical steel with an opening for releasing the clip marker, and a marking line, which shows the orientation of the ejection port for the clip marker. The handle is provided with a slider by means of which the clip can be released. The clip marker is situated in the distal ramp. TUMARK® Flex can be used together with, e.g. ultrasound and stereotactic X-ray imaging procedures.

The TUMARK® Flex is not indicated to be used in Magnetic Resonance Tomography (MRT). However, the clip marker placed in the patient can be exposed to a magnetic field of up to 3.0 Tesla, for instance in follow-up examinations.

Indications for Use:

The TUMARK® Flex is intended for radiographically and radiologically percutaneous marking of soft tissue, especially breast tissue, via a clip marker.

The TUMARK® Flex is not indicated to be used with magnetic resonance imaging (MRI) techniques.

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Summary of Safety and Effectiveness

Comparison to cleared devices (Substantial Equivalence):

The TUMARK® Flex is substantial equivalent to the TUMARK® Professional and MRI TUMARK® Professional, also manufactured by Somatex® Medical Technologies GmbH that have been cleared by FDA (K093064 and K073095). The TUMARK® Flex and TUMARK® Professional and MRI TUMARK® Professional are intended to attach a marker to soft tissue at the surgical site during a percutaneous procedure. All devices are indicated for use to radiographically and radiologically mark the surgical location in breasts following a percutaneous procedure.

In addition, both the proposed devices and the predicate devices are identical or similar in technology, design and material. In particular, the proposed devices and the predicate devices consist of the same primary components and the component materials of the proposed devices and the predicate devices are substantially equivalent and/or standard materials for invasive medical techniques. The minor technological differences between the proposed device and the predicate devices raise no new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Unterer Winkel 3
Wurmlingen 78573
Germany

NOV - 8 2011

Re: K111692
Trade/Device Name: TUMARK® Flex
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: II
Product Code: NEU
Dated: September 30, 2011
Received: October 17, 2011

Dear Mr. Jung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K111692

Indications for Use

510(k) Number (if known): _____

Device Name: **TUMARK® Flex**

Indications for Use:

The TUMARK® Flex is intended for radiographically and radiologically percutaneous marking of soft tissue, especially breast tissue, via a clip marker.

The TUMARK® Flex is not indicated to be used with magnetic resonance imaging (MRI) techniques.

Prescription Use YES (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use NO (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111692